

Description

CORRECTING FOOT ALIGNMENT

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application Serial No. 60/397,446, filed on July 19, 2002.

BACKGROUND OF INVENTION

FIELD OF THE INVENTION

[0002] The invention relates to correcting foot alignment. In one aspect, the invention relates to an apparatus for measuring the alignment of the human foot. In another of its aspects, the invention relates to a footwear corrective alignment insole kit for correcting foot alignment during standing, walking, or running. In another aspect, the invention relates to measuring instruments for determining the type and amount of corrective alignment required for a foot. In another aspect, the invention relates to a method for correcting the alignment of the human foot.

DESCRIPTION OF THE RELATED ART

[0003] No two human feet are the same. Indeed, an individual's two feet may have vastly different structural characteristics. For example, a person may have low arches, commonly referred to as "flat feet" or "fallen arches." Or, a person may suffer from pronation, i.e. the tendency of the foot to roll inward during walking or running. An individual with flexible ankles may suffer from painful pressure points that develop during walking or running due to the inability of the foot to maintain proper stability and alignment.

[0004] Different approaches are taken to correcting problems with foot alignment and structure. Exercises for strengthening the foot and/or ankles can be performed. However, these may be inadequate to correct structural problems such as a low arch. Alternatively, footwear corrective alignment insoles can be used to attempt to compensate for alignment and structural problems, particularly for raising and supporting a fallen arch. Or a corrective alignment insole can be used to stabilize the heel to prevent side-to-side movement of the foot. Frequently, corrective alignment insoles are inadequate to stabilize the foot during the full range of motion experienced during walking or running. Additionally, corrective alignment insoles are

generally located underneath the arch and heel portion of the foot, and do not extend beneath the plantar region of the foot and the toes. Consequently, as the foot rolls forward, weight is transferred off the corrective alignment insole which can affect the correction of the foot movement, even exacerbating the problems that the corrective alignment insole is intended to correct.

SUMMARY OF INVENTION

[0005] In a first embodiment of the invention, a method of making a shoe correction for the alignment of a person's foot, comprises the steps of, while the person is standing on the foot, inclining the person's lower leg forwardly about the foot a preselected angle from the vertical, and, while maintaining the person's lower leg in the forward inclined position at the preselected angle, measuring the lateral angular alignment of the foot. The method can further comprise the step of selecting from a database appropriate corrective components for incorporation into a shoe to correct the alignment of the person's foot, wherein the database has a correlation between a range of lateral angular alignment values and appropriate corrective components.

[0006] The corrective components can include combinations of

corrective alignment insole components, including supination, pronation, and arch control pads. The method can further comprise the step of constructing a corrective alignment insole from a base insole and the selected supination, pronation, and arch control pads.

[0007] The database can further include a correlation between lateral angular alignment values and an appropriate shoe type, and can further comprise the step of incorporating the corrective alignment insole into the selected shoe type.

[0008] The measuring step can be carried out with the aid of a subtalar joint goniometer. The measuring step can include the step of inscribing a reference line along the Achilles' tendon portion of the person's foot, and measuring the lateral angular alignment of the reference line. The method can further comprise the step of constructing a corrective alignment shoe by incorporating into the shoe the selected corrective components.

[0009] In an alternate embodiment, a method of making a shoe correction for the alignment of a person's foot can comprise the steps of measuring the lateral angular alignment of the person's foot with respect to a lower portion of the leg, and selecting from a database appropriate corrective

components for incorporation into a shoe to correct the alignment of the person's foot.

[0010] In yet another embodiment, a kit for quantifying and making a shoe correction for a misalignment of a person's foot comprises a dorsiflexion template adapted to position the person's lower leg at a preselected forward angle with respect to an upper surface of the person's foot adjacent the ankle when the person is standing on the foot, and a subtalar joint inclinometer to measure the lateral angular alignment of the person's foot when the person's lower leg is inclined at the preselected angle. The kit can further comprise at least one corrective alignment insole component comprising a base insole in the general shape of a person's footprint having a lateral portion, a medial portion, and an arch stability portion, at least one supination control pad for adjusting the supination alignment of the person's foot, at least one pronation control pad for adjusting the pronation alignment of the person's foot, and at least one arch control pad for adjusting the support of the person's arch.

[0011] The kit can further comprise a database which correlates a range of lateral angular alignment values combinations with at least one of the corrective alignment insole com-

ponents, wherein the at least one of the corrective alignment insole components can be selected from the database based upon the lateral angular alignment measurement obtained from the subtalar joint inclinometer.

[0012] The subtalar joint inclinometer can comprise a subtalar joint goniometer comprising a base portion having an indicator arrow extending orthogonally upwardly therefrom and an alignment portion pivotally attached to the base portion having a protractor scale inscribed thereon. The subtalar joint inclinometer can also comprise a calcaneal bisection gauge comprising a pair of arcuate wings pivotably connected by a hinge to locate the mid-line of the person's heel, and an angle finder to measure the inclination of the mid-line.

[0013] In another embodiment of the invention, a corrective alignment insole assembly for making a shoe correction for the alignment of a person's foot comprises a base insole in the general shape of a person's footprint having a lateral portion, a medial portion, and an arch stability portion, and adapted for correcting both pronation and supination in combination with at least one of at least one supination control pad, at least one pronation control pad, or at least one arch control pad, at least one supination

control pad for adjusting the supination alignment of the person's foot at least one pronation control pad for adjusting the pronation alignment of the person's foot, and at least one arch control pad for adjusting the support of the person's arch, wherein the at least one supination control pad, the at least one pronation control pad, and the at least one arch control pad are selected based upon a lateral angular alignment measurement of the person's foot.

[0014] The base insole can be divided into an irregularly-shaped supination control portion extending along the lateral portion of the base insole, an irregularly-shaped motion control portion extending along the medial portion of the base insole, and a crescent-shaped arch stability portion extending along the arch portion of the base insole.

[0015] The at least one supination control pad can comprise an irregularly-shaped member having a variable wedge-shaped cross section corresponding in size and shape to the supination control portion of the base insole, and having an anterior end, a posterior end, a medial edge, and a lateral edge, wherein the thickness of the at least one supination control pad decreases from the lateral edge to the medial edge, and from a portion along the

lateral edge to the anterior end and the posterior end. The at least one supination control pad can range in thickness from a maximum of $\frac{3}{16}$ inch at the center lateral edge to $\frac{1}{16}$ inch at the posterior end, to zero inches at the anterior end and along the medial edge. The at least one supination control pad can further comprise an irregularly-shaped central portion.

[0016] A supplementary supination control pad can comprise an irregularly-shaped member having a generally wedge-shaped cross section corresponding in size and shape to the supplementary supination control pad portion, attached to the supination control pad at a central portion thereof the supplementary supination control pad portion for increasing the maximum thickness of the supination control pad at its center lateral portion, and having an anterior end, a posterior end, a medial edge, and a lateral edge, wherein the thickness of the supination control pad decreases from the lateral edge to the medial edge, and from a portion along the lateral edge to the anterior end and the posterior end. The supplementary supination control pad can vary in thickness from a maximum of $\frac{1}{8}$ inch at the center lateral edge to zero inches at the anterior end, the posterior end, and the medial edge.

[0017] The at least one motion control pad can comprise an irregularly-shaped elongated member having a variable wedge-shaped cross section corresponding in size and shape to the motion control portion of the base insole, and having an anterior end, a posterior end, a medial edge, and a lateral edge, wherein the thickness of the at least one motion control pad decreases from the medial edge to the lateral edge, and from the portion along the medial edge to the anterior end and the posterior end. The at least one motion control pad can range in thickness from a maximum of 3/16-inch along the anterior portion of the medial edge, to 1/8-inch at the posterior end, to zero inches at the anterior end and along the lateral edge.

[0018] The at least one motion control pad can comprise an irregularly-shaped supplementary motion control pad portion located at the anterior medial portion of the at least one motion control pad. The supplementary motion control pad can comprise an irregularly-shaped member having a generally wedge-shaped cross-section corresponding in size and shape to the supplementary motion control pad portion, attached to the motion control pad at the supplementary motion control pad portion for increasing

the maximum thickness of the motion control pad at its anterior medial portion, and having an anterior end, a posterior end, a medial edge, and a lateral edge, wherein the thickness of the at least one supplementary motion control pad decreases from the center medial edge to the anterior end, the posterior end, and the lateral edge. The supplementary motion control pad can vary in thickness from a maximum of 1/8 inch at the center medial edge to zero inches at the anterior end, the posterior end, and the lateral edge.

[0019] The at least one arch stability pad can comprise a crescent-shaped member having a generally wedge-shaped cross section corresponding in size and shape to the arch stability portion of the base insole, and having an anterior end, a posterior end, a medial edge, and a lateral edge, wherein the thickness of the at least one arch stability pad decreases from the center medial edge to the lateral edge, the anterior end and the posterior end. The at least one arch stability pad can range in thickness from a maximum of 3/16 inch at the center medial edge to zero inch from the anterior end along the lateral edge to the posterior end.

[0020] The at least one arch stability pad can comprise a supple-

mentary arch stability pad comprising a crescent-shaped member having a generally wedge-shaped cross-section for attachment to the at least one arch stability pad for increasing the maximum thickness of the at least one arch stability pad at the arch stability portion of the base insole, and having an anterior end, a posterior end, a medial edge, and a lateral edge, wherein the thickness of the supplementary arch stability pad decreases from the center medial edge to the lateral edge, the anterior end, and the posterior end. The supplementary arch stability pad can vary in thickness from a maximum of 3/16 inch at the center medial edge to zero inch from the anterior end along the lateral edge to the posterior end.

[0021] The base insole can further comprise a resilient heel cushioning zone for cushioning impact to the heel. The resilient heel cushioning zone can comprise a pattern of cutout sections adapted to provide resilient cushioning immediately beneath the person's heel, or a low density gel pad adapted to provides resilient cushioning immediately beneath the person's heel. The low density gel pad can comprise a low density gel polymer.

[0022] In yet another embodiment, a subtalar joint inclinometer for measuring the lateral angular alignment of a person's

foot when the person is in a standing position comprises an instrument having at least one pivotable wing for aligning the instrument with the person's Achilles tendon and determining a reference line thereof, and an angle gauge for determining the inclination of the reference line from a vertical direction when the person is in the standing position. The subtalar joint inclinometer can comprise a base portion having an indicator arrow extending orthogonally upwardly therefrom and an alignment portion pivotally attached to the base portion having a protractor scale inscribed thereon, wherein the base portion is placed under the person's foot when the person is in the standing position, and the alignment portion is aligned with the person's Achilles tendon so that a lateral angular alignment value can be determined by reference to the protractor scale. The subtalar joint inclinometer can also comprise a calcaneal bisection gauge for inscribing the reference line and a protractor for determining the inclination of the reference line.

[0023] In yet another embodiment of the invention, a database for selecting at least one corrective alignment insole component for making a shoe correction for a misalignment of a person's foot based upon a measurement of a lateral

angular alignment of the person's foot comprises a plurality of preselected lateral angular alignment values, and at least one corrective alignment insole component, wherein the preselected lateral angular alignment values are correlated to the at least one corrective alignment insole component so that the at least one corrective alignment insole component can be selected from the database based upon the lateral angular alignment measurement. The database can further include a correlation between the plurality of lateral angular alignment values with a variety of shoe types and wherein the appropriate corrective shoe can be selected for use with the selected at least one corrective alignment insole component. The at least one corrective alignment insole component can include at least one of a base insole, a supination control pad, a supplementary supination control pad, a motion control pad, and a supplementary motion control pad. A lateral angular alignment value of -5° to 3° can correlate to an assembly of corrective alignment insole components comprising a base insole, a supination control pad, and a supplementary supination control pad.

[0024] A lateral angular alignment value of 3° to 6° can correlate to an assembly of corrective alignment insole components

comprising a base insole, and a supination control pad. A lateral angular alignment value of 6° to 9° can correlate to an assembly of corrective alignment insole components comprising a base insole. A lateral angular alignment value of 9° to 12° can correlate to an assembly of corrective alignment insole components comprising a base insole, and a supplementary motion control pad.

[0025] A lateral angular alignment value of 12° to 15° can correlate to an assembly of corrective alignment insole components comprising a base insole, and a motion control pad. A lateral angular alignment value of greater than 15° can correlate to an assembly of corrective alignment insole components comprising a base insole, a motion control pad, and a supplementary motion control pad.

BRIEF DESCRIPTION OF DRAWINGS

[0026] In the drawings:

[0027] Figure 1 is a rear elevational view of a human foot showing misalignment of the leg, ankle, and foot due to a fallen arch.

[0028] Figure 2 is a rear elevational view of a human foot showing correction of the misalignment of Figure 1 from the utilization of a corrective alignment insole according to

the invention.

- [0029] Figure 3 is a side elevational view of a human foot showing the proper positioning of the leg, ankle, and foot utilizing a dorsiflexion template according to the invention.
- [0030] Figure 4 is a rear elevational view of the foot of Figure 3 showing the angular alignment of the leg, ankle, and foot utilizing a subtalar joint goniometer instrument according to the invention.
- [0031] Figure 5 is a plan view of the dorsiflexion template of Figure 3.
- [0032] Figure 6 is a perspective view of the subtalar joint goniometer instrument of Figure 4.
- [0033] Figure 7 is an exploded plan view of the subtalar joint goniometer instrument of Figure 4.
- [0034] Figure 8 is a bottom plan view of a base insole comprising a first component of a footwear corrective alignment insole according to the invention and an embodiment of a resilient heel cushioning zone.
- [0035] Figure 9 is an exploded perspective view from underneath of a motion control pad and a supplementary motion control pad comprising a second component of a footwear corrective alignment insole according to the invention.
- [0036] Figure 10 is a sectional view of the motion control pad

shown in Figure 9 taken along line 10–10 of Figure 9.

[0037] Figure 11 is a sectional view of the motion control pad shown in Figure 9 taken along line 11–11 of Figure 9.

[0038] Figure 12 is an exploded perspective view from underneath of a supination control pad and a supplementary supination control pad comprising a third component of a footwear corrective alignment insole according to the invention.

[0039] Figure 13 is a sectional view of the supination control pad shown in Figure 12 taken along line 13–13 of Figure 12.

[0040] Figure 14 is a sectional view of the supination control pad shown in Figure 12 taken along line 14–14 of Figure 12.

[0041] Figure 15 is an exploded perspective view from underneath of an arch stability pad and a supplementary arch stability pad comprising a fourth component of a footwear corrective alignment insole according to the invention.

[0042] Figure 16 is a sectional view of the arch stability pad shown in Figure 15 taken along line 16–16 of Figure 15.

[0043] Figure 17 is a sectional view of the arch stability pad shown in Figure 15 taken along line 17–17 of Figure 15.

[0044] Figure 18 a perspective view of a calcaneal bisection gauge according to the invention.

[0045] Figure 19 is a perspective view of the use of the calcaneal

bisection gauge of Figure 18 to draw a calcaneal bisection line on a heel.

[0046] Figure 20 is a rear elevational view of a foot showing the calcaneal bisection line drawn on the heel.

[0047] Figure 21 is a database chart according to the invention for selecting one or more pads for assembly into a corrective alignment insole to correct a misalignment of a foot.

[0048] Figure 22 is a foot/leg symptomatic chart for correlating a corrective alignment insole with reported foot, leg, and hip symptoms according to the invention.

[0049] Figure 23 is a perspective view of an evaluation of a subtalar neutral position.

[0050] Figure 24 is a perspective view of an evaluation of the angular misalignment of the foot width of the lower leg inclined 25°.

[0051] Figure 25 is a perspective view of a non-weight bearing evaluation of the alignment of the foot.

[0052] Figure 26 is a view of a foot and a leg of a patient lying in a prone position showing a non-weight bearing evaluation of the alignment of the foot.

[0053] Figure 27 is an exploded view showing the assembly of the pads of Figures 9, 12, and 15 onto the base insole of Figure 8 to form a corrective alignment insole according

to the invention.

[0054] Figure 28 is a plan view of the base insole shown in Figure 8 comprising an alternate embodiment of a resilient heel cushioning zone comprising a low density gel pad.

[0055] Figure 29 is a perspective view of the low density gel pad shown in Figure 28.

[0056] Figure 30 is a sectional view of the low density gel pad shown in Figure 29 taken along line 30-30 of Figure 29.

DETAILED DESCRIPTION

[0057] The foot has three main parts: the forefoot, the midfoot, and the hindfoot. The forefoot comprises the five toes, or phalanges, and their connecting long bones, i.e. the metatarsals. The midfoot comprises five irregularly-shaped tarsal bones, forms the foot's arch, and serves as a "shock absorber" during walking, running, or jumping. The bones of the midfoot are connected to the forefoot and the hindfoot by muscles and the plantar fascia, or the arch ligament. The hindfoot is composed of three joints and links the midfoot to the ankle, called the talus. The top of the talus is connected to the two long bones comprising the lower leg, i.e. the tibia and the fibula, forming a hinge that allows the foot to move up and down. The heel bone, or calcaneus is the largest bone in the foot. It

joins the talus to form the subtalar joint, which enables the foot to rotate at the ankle.

[0058] Figure 1 shows a portion of a lower extremity 10 of a human illustrating misalignment of a heel 11, a leg 15, and ankle 17, and a foot 19 due to a structural anomaly. For exemplary purposes, the anomaly is shown as a condition commonly referred to as "fallen arches" or "flat feet." As a consequence of this condition, the ankle 17 is tilted inwardly, known as "pronation," and the lower leg 15 is inclined so that the foot 19, lower leg 15, knee, upper leg, and hip are vertically misaligned. This can result in an improper walking and running motion, placing the leg joints under stress, and increasing the potential for injury and pain.

[0059] Figure 2 shows a foot 19 supported on a corrective alignment insole 12 which corrects the misalignment of the foot due to, for example, "fallen arches" by raising the inner or medial portion of the foot 19 according to the invention. The corrective alignment insole 12 can also raise the outer or lateral portion of the foot 19 as necessary to correct other misalignments of the foot 19 and leg 15, as hereinafter described. The corrective alignment insole 12 also controls the motion of the foot 19 and the leg 15,

restoring the proper alignment of the foot 19 and leg 15 during walking and running.

[0060] The corrective alignment insole 12 is a component system comprising a base insole and wedge-shaped pads of progressively increasing thickness for raising and tilting selected portions of the foot 19. The corrective alignment insole 12 can be readily customized to a precise foot structure and required alignment correction because of the adaptability of the component system. The combination of insole and pads required to correct the misalignment is determined by the use of two instruments comprising the invention and a systematic evaluation of the structure of the foot 19, the ankle, and the leg 15.

[0061] Figures 3–7 show measuring instrumentation according to the invention. Figures 3–4 show the instrumentation in use. Figure 3 shows the first instrument, referred to herein as a "dorsiflexion template" 13, positioned against the foot 19 at the ankle 17. Referring to Figure 5, the dorsiflexion template 13 is a generally diamond-shaped, plate-like member having an ankle vertex 16, a upper edge 18, and a lower edge 20. The vertex 16, upper edge 18, and lower edge 20 define an obtuse angle α , preferably about 105°. The angle α represents the angle between

the leg 15 and the foot 19 at which the heel 11 just begins to lift from a supporting surface as the leg 15 is inclined forward, typically at an angle of about 25° from the vertical.

[0062] Referring now to Figure 4, a first embodiment of a subtalar joint inclinometer, referred to herein as a "subtalar joint goniometer" 14, is shown in position relative to the heel 11 for determining the lateral angular alignment of the foot 19. Referring also to Figures 6 and 7, the subtalar joint goniometer 14 is a two-piece, pivotably-interconnected angle measuring device comprising a base portion 22 and an alignment protractor 24. The base portion 22 is a generally trapezoidal-shaped, plate-like member comprising a heel plate 26, a pair of spaced apart upwardly-extending side walls 28 hingedly attached thereto, and an upwardly-extending rear wall 30 hingedly attached to the heel plate 26. The heel plate 26 is a generally trapezoidal-shaped member having a pair of spaced-apart edges 25 inclined toward the rear wall 30, and a rear edge 23. Each side wall 28 is attached to the heel plate 26 along the inclined edge 25 through a living hinge 27. The rear wall 30 is attached to the heel plate 26 along the rear edge 23 through a living hinge 29. As shown in Figure 4,

the heel plate 26, the side walls 28, and the rear wall 30 form a cradle-like structure into which the heel 11 is placed for measurement of the foot and leg alignment, as hereinafter described.

[0063] Extending upwardly from the rear wall 30, perpendicular to the heel plate 26, is a triangularly-shaped pointer 32. Extending through the back wall 30, in axial alignment with the pointer 32, is an aperture 34 for pivotably mounting the alignment protractor 24 to the base portion 22. In the preferred embodiment, the base portion 22 is formed from a sheet of material, such as a rigid plastic, or cardboard, and folded along the living hinges 27, 29 to form the cradle-like base portion 22.

[0064] The alignment protractor 24 is a generally irregularly-shaped member comprising an Achilles plate 36, a pair of spaced-apart wings 38 hingedly attached thereto, and an alignment scale 40 affixed to the Achilles plate 36, such as by printing or embossing. The Achilles plate 36 is an irregularly shaped member comprising a pair of spaced-apart inclined edges 33. Each wing 38 is a generally trapezoidal-shaped member extending laterally from the Achilles plate 36. Each wing 38 is attached to the Achilles plate 36 along the edge 33 through a living hinge 35. The

lower portion of the Achilles plate 36 terminates in a downwardly-depending, arcuately-shaped pivot flange 37. The pivot flange 37 is provided with a generally centrally-positioned pivot aperture 42 adapted to be aligned with the aperture 34. A pin 44 is received through the pivot aperture 42 and the aperture 34 for pivotable movement of the alignment protractor 24 relative to the base portion 22. Preferably, the alignment protractor 24 is fabricated of the same material as the base portion 22.

[0065] The dorsiflexion template 13 and the subtalar joint goniometer 14 can be made available to the public through an Internet website for downloading to a printer. Printing or transferring the dorsiflexion template 13 and the subtalar joint goniometer 14 onto a stiff material, such as cardboard, will enable a consumer to fabricate the instruments for personal or family use.

[0066] Referring to Figures 18, 19 and 24, an alternate subtalar joint inclinometer, comprising a calcaneal bisection gauge 110 and an angle finder 122, is shown. It is anticipated that the calcaneal bisection gauge 110 and the angle finder 122 will be used primarily by foot care professionals such as podiatrists and physicians. The calcaneal bisection gauge 110 is used to locate the mid-line of the

heel 11, and comprises a pair of arcuate wings 112, 114 pivotably connected by a hinge 116. The calcaneal bisection gauge 110 can be fabricated of any suitable material, such as a rigid or semi-rigid plastic, aluminum, or stainless steel. The preferred embodiment comprises a thermoplastic with the hinge 116 integrally formed as a living hinge. The hinge 116 terminates at each end in a pair of generally V-shaped spaced-apart notches 118, 120 longitudinally aligned with the hinge 116. The curvature of the wings 112, 114 and the action of the hinge 116 enable the calcaneal bisection gauge 110 to "grip" the heel 11. As shown in Figure 19, with the calcaneal bisection gauge 110 in position against the heel 11, a pair of angular marks are made on the heel 11 with a suitable marking instrument, such as a ball-point pen, and with the gauge 110 removed the apexes of the marks are connected to form a calcaneal bisection line 130 corresponding to the mid-line of the heel 11 (Figure 20).

[0067] The angle finder 122 comprises a suitable conventional protractor, such as a conventional carpenter's protractor, as shown in Figure 24, for determining the angle between the calcaneal bisection line 130 made using the calcaneal bisection gauge 110 and the vertical. The angle deter-

mined from the angle finder 122 is used to select the appropriate footwear corrective alignment insole pads, as hereinafter described.

[0068] Figures 8–17 show the various components of the corrective alignment insole pads according to the invention. The description which follows relates to corrective alignment insole pads that can be assembled and inserted into a shoe, preferably in place of the insole that is initially supplied with the shoe. However, the corrective alignment insole pads can also be initially incorporated into a shoe during manufacture so that the shoe is supplied to a purchaser with the corrective alignment insole pads already in place.

[0069] Referring to Figures 8–11, a base insole 50 comprises a generally plate-like foot-shaped member having a toe end 52 and a heel end 54. The base insole 50 may be flat, or somewhat curved to correspond to the general profile of the sole of a foot, particularly with a raised arch portion. The base insole 50 has an upper side 51 for contacting the foot 19, and an underside 53 for contacting the midsole of the footwear. In the preferred embodiment, the base insole 50 and hereinafter described pads are provided in a variety of lengths and widths to accommodate a

suitable range of foot sizes.

[0070] The base insole 50 comprises a layered structure comprising a supporting shell, an overlying cellular foam layer, and a breathable polyester fabric cover. The shell is preferably fabricated of a semi-rigid plastic, such as polyurethane. The foam layer can be a closed-cell foam or an open-cell foam depending on the degree of cushioning and support desired. As shown in Figure 8, the heel end 54 is provided with a heel shock absorption grid 62 generally at the center thereof, and comprising a pattern of cutout sections in the cellular foam layer which provides a resilient cushioning zone immediately beneath the heel 11. The underside 53 of the base insole 50 is provided with a plurality of selectively positioned alignment apertures 64 extending into the base insole 50.

[0071] An alternative resilient heel cushioning zone is shown in Figures 28–30. Instead of the heel shock absorption grid 62, a low density gel pad 134 is added to the heel end 54. The low density gel pad 134 is shown in Figures 28 and 29 as a circular-shaped pad comprising a circular center pedestal 136 with an annular perimeter flange 138 extending radially outwardly therefrom. Preferably, the perimeter flange 138 is tapered toward its perimeter. Al-

ternatively, the gel pad 134 can be an oval or other shape suitable for incorporating into the heel end 54. As shown in Figures 29 and 30, the gel pad 134 is provided with a plurality of suitably-spaced circular recesses 140 adapted for controlling the cushioning properties of the pad 134. The size, number, and depth of the recesses 140 can be selected to provide a pre-selected degree of resilience and cushioning to the gel pad 134.

[0072] In the embodiment shown in Figures 28–30, the base insole 50 is provided with a circular recess or cutout adapted to receive the center pedestal 136 so that the perimeter flange 138 lays over the base insole 50. The insertion of the center pedestal 136 in the recess/cutout prevents the gel pad 134 from shifting during use. Preferably, the gel pad 134 comprises a low density gel polymer, although other materials can be employed based upon the degree of resilience and cushioning desired.

[0073] The base insole 50 is divided into a supination control portion 56 extending along the lateral portion of the base insole 50 (identified by the dotted line in Figure 8), a motion control portion 58 extending along the medial portion of the base insole 50 (identified by the combined dashed and dotted line in Figure 8), and an arch stability

portion 60 extending along the arch portion of the base insole 50 (identified by the dotted line in Figure 8).

[0074] As shown in Figure 9, a motion control pad 70 is an irregularly-shaped generally elongated member having a variable wedge-shaped cross section corresponding in size and shape to the motion control portion 58 of the base insole 50, and having an anterior end 71, a posterior end 73, a medial edge 75, a lateral edge 77, an obverse side 79, and a reverse side 80. The motion control pad 70 is preferably fabricated of EVA, with a cross-section as shown in Figures 10 and 11, and is attached to the underside 53 of the base insole 50 at the motion control portion 58. The thickness of the motion control pad 70 decreases from the medial edge 75 to the lateral edge 77, and from the portion along the medial edge 75 to the anterior end 71 and the posterior end 73. Preferably, the motion control pad 70 ranges in thickness from a maximum of 3/16-inch along the anterior portion of the medial edge 75, to 1/8-inch at the posterior end 73, to zero inches at the anterior end 71 and along the lateral edge 77. In Figure 9, the thicknesses of the motion control pad 70 are indicated in parentheses.

[0075] The motion control pad 70 is provided with an irregularly-

shaped supplementary motion control pad portion 69 located at the anterior medial portion of the motion control pad 70 (identified by the dotted outline in Figure 9). The reverse side 80 of the motion control pad 70 is provided with a plurality of alignment posts 66 for insertion into the mating alignment apertures 64 of the motion control portion 58 of the base insole 50 for attaching the motion control pad 70 to the base insole 50. The obverse side 79 of the supplementary motion control pad portion 69 is provided with a plurality of selectively positioned alignment apertures 64 extending into the motion control pad 70.

[0076] As also shown in Figure 9, a supplementary motion control pad 76 is an irregularly-shaped member, preferably fabricated of EVA, having a generally wedge-shaped cross-section corresponding in size and shape to the supplementary motion control pad portion 69, and is attached to the motion control pad 70 at the supplementary motion control pad portion 69 for increasing the maximum thickness of the motion control pad 70 at its anterior medial portion. The supplementary motion control pad 76 has an anterior end 100, a posterior end 102, a medial edge 104, a lateral edge 106, an obverse side 107,

and a reverse side 108. Preferably, the supplementary motion control pad 76 varies in thickness from a maximum of 1/8 inch at the center medial edge 104 to zero inches at the anterior end 100, the posterior end 102, and the lateral edge 106.

[0077] The reverse side 108 of the supplementary motion control pad 76 is provided with a plurality of alignment posts 66 for insertion into the mating alignment apertures 64 of the supplementary motion control pad portion 69 for attaching the supplementary motion control pad 76 to the motion control pad 70. Alternatively, the supplementary motion control pad 76 can be attached directly to the base insole 50.

[0078] Referring now to Figure 12, a supination control pad 68 is an irregularly-shaped member having a variable wedge-shaped cross section corresponding in size and shape to the supination control portion 56 of the base insole 50, and having an anterior end 61, a posterior end 63, a medial edge 65, a lateral edge 67, an obverse side 81, and a reverse side 82. The supination control pad 68 is preferably fabricated of EVA, with a cross section as shown in Figures 13 and 14, and is attached to the underside 53 of the base insole 50 at the supination control portion 56.

The thickness of the supination control pad 68 decreases from the lateral edge 67 to the medial edge 65, and from the portion along the lateral edge 67 to the anterior end 61 and the posterior end 63. Preferably, the supination control pad 68 ranges in thickness from a maximum of 3/16 inch at the center lateral edge to 1/16 inch at the posterior end 63, to zero inches at the anterior end 61 and along the medial edge 65. In Figure 12, the thicknesses of the supination control pad 68 are indicated in parentheses.

[0079] The supination control pad 68 is provided with an irregularly-shaped supplementary supination control pad portion 57 located at the center lateral portion of the supination control pad 68 (identified by the dotted outline in Figure 12). The reverse side 82 of the supination control pad 68 is provided with a plurality of alignment posts 66 for mating communication with the alignment apertures 64 of the supination control portion 56 of the base insole 50 for attaching the supination control pad 68 to the base insole 50. The obverse side 81 of the supplementary supination control pad portion 57 is provided with a plurality of selectively positioned alignment apertures 64 extending into the supination control pad 68.

[0080] As also shown in Figure 12, a supplementary supination control pad 74 is an irregularly-shaped member, preferably fabricated of EVA, having a generally wedge-shaped cross section corresponding in size and shape to the supplementary supination control pad portion 57, and is attached to the supination control pad 68 at the supplementary supination control pad portion 57 for increasing the maximum thickness of the supination control pad 68 at its center lateral portion. The supplementary supination control pad 74 has an anterior end 101, a posterior end 103, a medial edge 105, a lateral edge 98, an obverse side 99, and a reverse side 109. Preferably, the supplementary supination control pad 74 varies in thickness from a maximum of 1/8 inch at the center lateral edge 98 to zero inches at the anterior end 101, the posterior end 103, and the medial edge 105.

[0081] As shown in Figure 15, an arch stability pad 72 is a generally crescent-shaped member having a generally wedge-shaped cross section corresponding in size and shape to the arch stability portion 60 of the base insole 50, and having an anterior end 83, a posterior end 84, a medial edge 85, a lateral edge 86, an obverse side 87, and a reverse side 88. The arch stability pad 72 is preferably fab-

ricated of EVA, with a cross-section as shown in Figures 16 and 17, and is attached to the underside 53 of the base insole 50 at the arch stability portion 60. The thickness of the arch stability pad 72 decreases from the center medial edge 85 to the lateral edge 86, the anterior end 83 and the posterior end 84. Preferably, the arch stability pad 72 ranges in thickness from a maximum of 3/16 inch at the center medial edge 85 to zero inch from the anterior end 83 along the lateral edge 86 to the posterior end 84. In Figure 15, the thicknesses of the arch stability pad 70 are indicated in parentheses.

[0082] The reverse side 88 of the arch stability pad 72 is provided with a plurality of alignment posts 66 for mating communication with the alignment apertures 64 of the arch stability portion 60 of the base insole 50 for attaching the arch stability pad 72 to the base insole 50. The obverse side 87 of the arch stability pad 72 is provided with a plurality of selectively positioned alignment apertures 64 extending into the arch stability pad 72 for attachment of a supplemental arch stability pad 78.

[0083] As also shown in Figure 15, a supplementary arch stability pad 78 is a generally crescent-shaped member, preferably fabricated of EVA, having a generally wedge-shaped

thickness for attachment to the arch stability pad 72 for increasing the maximum thickness of the arch stability pad 72 at the arch stability portion 60 of the base insole 50. The supplementary arch stability pad 78 has an anterior end 89, a posterior end 90, a medial edge 91, a lateral edge 92, an obverse side 93, and a reverse side 94. Preferably, the supplementary arch stability pad 78 varies in thickness from a maximum of 3/16 inch at the center medial edge 91 to zero inch from the anterior end 89 along the lateral edge 92 to the posterior end 90. In Figure 15, the thicknesses of the supplemental arch stability pad 78 are indicated in parentheses.

[0084] Figure 27 shows the base insole 50 with the proper positioning of the supination control pads 68, 74, the motion control pads 70, 76, and the arch stability pads 72, 78 on the underside 53 of the base insole 50 to form the corrective alignment insole 12 as herein described. The insole 50 can be utilized with or without pads as determined by the measurements described herein. The measurements are used to determine specific pads to be attached to the base insole 50 to form a corrective alignment insole 12, as hereinafter described. The corrective alignment insole 12, incorporating selected pads, can be utilized as an in-

sole to be placed by the user in a selected shoe after removing the original insole. In such a case, only one pair of corrective alignment insoles 12 is needed. Alternatively, a corrective alignment insole as described herein can be incorporated into a shoe as the original insole, thereby rendering the shoe a complete corrective alignment shoe. A user would then select a style of shoe having the required corrective alignment insole already installed.

[0085] Figure 21 shows a database embodied in a chart for determining the particular combination of corrective alignment insole components needed based upon the results from the measurements obtained with the dorsiflexion template 13 and the subtalar joint goniometer 14, or alternatively the calcaneal bisection gauge 110 and the angle finder 122. Figure 22 shows a foot/leg symptomatic database embodied in a chart for use with the database chart of Figure 21 for refining the selection of corrective alignment insole components based upon a patient's description of various foot and leg symptoms. Alternatively, the databases can be embodied in a suitable alternate form, such as a computer database in digital form, or the like. These databases are used as part of a diagnostic and therapeutic method for systematically evaluating the mis-

alignment of the patient's foot and leg, and selecting the necessary corrective alignment insole pads to correct the misalignment and reducing the patient's symptoms. This diagnostic and therapeutic method will now be described.

[0086] It is anticipated that the dorsiflexion template 13 and the subtalar joint goniometer 14 will be utilized by footwear sales personnel and the consumer, whereas the calcaneal bisection gauge 110 and the angle finder 122 will be used by podiatrists, orthopedic surgeons, and other footcare specialists. However, it will be understood that the use of the instruments is not so limited and that any of the instruments can be successfully utilized by a person having an understanding of their proper use.

[0087] There are five generally-recognized foot types which are quantified through the use of the method and instruments described herein. These include over-supination, mild supination, neutral, mild pronation, and over-pronation. The unique method described herein further divides over-pronation into two subcategories based upon the degree of angular displacement of the foot. Supination refers to the tendency of the foot to roll outwardly or laterally during walking or running. Pronation refers to the tendency of the foot to roll inwardly or medially during walking or

running. The patient's description of his or her foot and leg symptoms is used with the foot/leg symptomatic chart (Figure 22) to identify likely corrective alignment insole pads and any medical conditions that may require additional diagnosis and treatment.

[0088] Shoes are frequently manufactured with selected structural qualities to accommodate the different foot types described herein. Thus, certain shoes will be preferred for a pronating foot, while other shoes will be preferred for a supinating foot. These shoe types and the associated foot types are set out in the foot/leg symptomatic chart of Figure 22. The measurements obtained with the dorsiflexion template 13 and the subtalar joint goniometer 14, or the calcaneal bisection gauge 110 and the angle finder 122, are used to place the patient's foot into one of the above foot types using the measurement chart (Figure 21), select a recommended shoe type, and select the corrective alignment insole components.

[0089] For example, having determined the angular alignment of the foot as herein described and obtained a measurement of 10 degrees, the database chart prescribes a shoe providing full stability having a corrective alignment insole to correct mild pronation comprising a neutral base insole

50 with a supplementary motion control pad 76, identified in the measurement chart 130 as a "D" corrective alignment insole.

[0090] The dorsiflexion template 13 and the subtalar joint goniometer 14 are utilized as shown in Figures 3 and 4. The dorsiflexion template 13 is placed at the front apex of the ankle 17 between the leg 15 and the foot 19, and the leg 15 is inclined forward so that the leg 15 contacts the upper side 18 of the dorsiflexion template 13 and the foot 19 contacts the lower side 20 of the dorsiflexion template 13, thus orienting the leg 15 at the proper inclination for use of the subtalar joint goniometer 14. While the inclination of the leg 15, as determined with the dorsiflexion template 13, is maintained, the heel 11 is placed on the heel plate 26 in contact with the alignment protractor 24 so that the heel 11 can be "wrapped" with the wings 38, as shown in Figure 4. The alignment protractor 24 will thus be placed in proper orientation relative to the heel 11 and the ankle 17. The angular alignment of the heel 11 and the ankle 17 can then be read from the alignment protractor 24. The angle thus determined is used with the database chart of Figure 21 to select the proper corrective alignment insole 12 and footwear.

[0091] Alternatively, a footcare professional can use the dorsi-flexion template 13 and the subtalar joint goniometer 14, or the calcaneal bisection gauge 110 and the angle finder 122, in combination with a medical evaluation, to determine the angle of alignment and the proper corrective alignment insole 12 and footwear from the database chart of Figure 21. The following description assumes that the footcare professional will utilize the calcaneal bisection gauge 110 and the angle finder 122.

[0092] Preferably, a sequence of specific steps is taken in utilizing the invention. The method of utilizing the information to select a corrective alignment insole includes a sequence of evaluation steps comprising a standing visual assessment or "weight-bearing" assessment, a non-weight-bearing or prone measurement, and subtalar joint measurements using the subtalar joint goniometer 14. The standing visual assessment and prone measurement involve observational and diagnostic techniques familiar to a person of ordinary skill in orthopedics, podiatry, and other medical arts related to the feet, although these techniques are utilized in a novel way in conjunction with the unique subtalar joint measurements to identify the proper corrective alignment insole.

[0093] During the "weight-bearing" assessment, three measurements are taken. The first is an evaluation of the subtalar neutral position. The evaluation is performed with a patient initially in a prone position. With the patient in the prone position, the calcaneal bisection gauge 110 is used to establish the calcaneal bisection line 130 as heretofore described. The patient then stands with his or her knees approximately four inches apart (i.e. a "fist width" apart). The medial and lateral heads of the talus bone are palpated while the patient rotates his or her hips from side to side until both heads of the talus bone can be palpated evenly on both sides (Figure 23). While the patient holds that position, the subtalar joint goniometer 14 or angle finder 122 are used to determine the heel angle. This angle defines the subtalar neutral position, and is recorded.

[0094] The next measurement is an evaluation of the "relaxed" position. The patient stands in an upright, relaxed posture with the feet slightly apart in a natural position. A second measurement of the heel angle is taken and recorded.

[0095] The final measurement defines 25° of standing dorsiflexion. For this measurement, the patient stands with his or her feet spread slightly apart and squats until the Achilles area of the heel 11 is inclined 25° from the vertical.

Twenty-five degrees is determined either by a direct angular measurement using the angle finder 122, as shown in Figure 24, or by using the dorsiflexion template 13.

While the patient holds this position, the heel angle, as defined by the calcaneal line, is determined and recorded.

[0096] The non-weight-bearing assessment is performed with the patient lying face-down on an evaluation table with both feet extending off the edge of the table. Both heads of the talus bone are palpated while the fifth metatarsal head is grasped so that the ankle 17 can be rotated from side to side (Figure 25). The ankle 17 is rotated until the talus heads are even on both sides. When the point is reached at which the talus heads are even, gentle pressure is placed on the bottom of the fifth metatarsal head to force the foot into dorsiflexion (Figure 26). The foot will assume one of three orientations: neutral, i.e. effectively no misalignment, varus, i.e. a supinated alignment, or valgus, i.e. a pronated alignment. These findings are recorded for later reference.

[0097] The following represents expected normal ranges of measurement:

[0098] Weight-Bearing: 0°–3°

[0099] Non-Weight-Bearing: 4°–6°

[0100] Standing Dorsiflexion: 7°–9°

[0101] The difference between the weight-bearing measurement and the standing dorsiflexion measurement represents the total pronation. A value of 6° or less frequently indicates a tendency toward oversupination. A value of 10° or greater frequently indicates a tendency toward overpronation. If the weight-bearing measurement is different than the non-weight-bearing measurement, the foot is referred to as a "compensated foot." Conversely, if the weight-bearing measurement is the same as the non-weight-bearing measurement, the foot is referred to as an "uncompensated foot."

[0102] The total pronation measurement, i.e. the difference between the weight-bearing measurement and the standing dorsiflexion measurement, is used to determine the correct corrective alignment insole from the database chart (Figure 21). The database chart is also utilized to identify the shoe type with which the corrective alignment insole should be used. The foot/leg symptomatic chart (Figure 22) can also be used as an initial diagnostic chart or to further confirm or refine the selection of the corrective alignment insole type from the database chart. The symptomatic chart identifies common symptoms which many

patients describe and which can be alleviated by the proper corrective alignment insole. For example, the foot/leg symptomatic chart indicates that lateral shin pain may be alleviated through a type A or B corrective alignment insole. A total pronation measurement of 4°, indicating mild supination and the use of a type B corrective alignment insole, would confirm the selection of a type B corrective alignment insole as indicated by the patient's complaint of lateral shin pain.

[0103] As an alternative to the database chart shown in Figure 21, the subtalar joint goniometer measurements can be incorporated into a computerized database and correlated with shoe type information and specific combinations of corrective alignment insole components in a computerized program for quickly selecting proper shoe types and corrective alignment insole components for a range of subtalar joint goniometer measurements.

[0104] The method of measuring the alignment of a foot and the selection of a shoe type and corrective alignment insole components can be formalized into a sequence of steps, which can be incorporated into a comprehensive computer program.

[0105] The method can include the following steps:-

- [0106] While standing, inclining the leg approximately 25° from the vertical utilizing a dorsiflexion template;
- [0107] While maintaining the leg in the inclined position, taking a measurement of the lateral angular alignment of the foot utilizing a subtalar joint goniometer;-
- [0108] Reading the lateral angular alignment value from the subtalar joint goniometer;-
- [0109] Referring the lateral angular alignment value to a database chart which correlates a range of lateral angular alignment values from a subtalar joint goniometer with shoe types and combinations of corrective alignment insole components;-
- [0110] Selecting a shoe type and a combination of corrective alignment insole components from the database chart corresponding to the lateral angular alignment value obtained from the subtalar joint goniometer measurement;-
- [0111] Constructing a corrective alignment insole from a base insole and one or more supination or pronation control pads and arch control pads identified in the database chart corresponding to the lateral angular alignment value obtained from the subtalar joint goniometer measurement;-and
- [0112] Utilizing the corrective alignment insole to correct the

alignment of the foot by incorporating the corrective alignment insole into the shoe type identified in the database chart corresponding to the lateral angular alignment value obtained from the subtalar joint goniometer measurement.

[0113] Prevention and correction of biomechanical injuries to the lower extremities is possible with the novel corrective system described herein. Utilizing the unique measuring tools as described herein, footcare specialists, shoe stores, and consumers can select appropriate footwear and a customized corrective alignment insole quickly and accurately, thereby enhancing the effectiveness of the foot alignment correction and decreasing costs. Unlike prior art corrective alignment insoles, the novel corrective system described herein focuses corrective action away from the arch alone and onto the entire foot and its biomechanical behavior during walking or running. The corrective alignment insole can be accurately customized by selecting a specific combination of the unique support pads for any of six different foot types and arch heights. Ankle mobility is controlled using support pads specifically configured and combined for motion control, stability, neutral conditions, or supination control.

[0114] While the invention has been specifically described in connection with certain specific embodiments thereof, it is to be understood that this is by way of illustration and not of limitation, and the scope of the appended claims should be construed as broadly as the prior art will permit.